



## Quality Management Overview

San Diego Blood Bank is committed to meet or exceed the quality requirements of our customers, federal, state and local regulatory agencies as well as AABB Standards. This commitment is achieved and maintained by the following:

### Critical Control Points:

1. Organizational Issues
2. Personnel Selection, Training, and Education
3. Validation, Calibration, Preventive Maintenance, and Proficiency Testing
4. Supplier Qualification
5. Process Control
6. Documentation and Record Review
7. Lot Release and Label Control
8. Incident, Accident, and Error Management
9. Auditing
10. Process Improvement
11. Safety and Facilities

San Diego Blood Bank continuously measures and evaluates the results of the critical control points listed above to provide continuous improvement of blood services management and operating systems.

### Regulatory and Accreditation Compliance

San Diego Blood Bank follows all laws, regulations and standards required. The blood center holds several licenses and accreditations including license and registration with the Food and Drug Administration, California State Biologics license and Clinical Laboratory license, CMS/CLIA accreditation and AABB accreditation. Copies of all licenses, registrations, and accreditations are available on the San Diego Blood Bank web site at [sandiegobloodbank.org](http://sandiegobloodbank.org).

### Donor Testing and Customer Notification in the Event of Positive Test Results or Post Donation Information

As per FDA and California Department of Public Health regulations all donor blood is tested for infectious disease markers. San Diego Blood Bank customers are notified within 3 days for in-date blood products that are positive for HIV and HCV test results at the time of a subsequent donation or otherwise determined to be at increased risk for transmitting HIV or HCV. Additionally, hospital customers are notified in writing within 45 days of any supplemental or follow up donor test results.



## **Sterility**

The San Diego Blood Bank employs aseptic methods to minimize the risk of bacterial contamination of blood and blood components including single use blood bags and needles. All equipment and solutions that come into direct contact with blood or blood components are sterile and pyrogen free. Additionally, San Diego Blood Bank uses the bioMerieux BacT/Alert 3 D System to detect bacteria in all apheresis platelet components. This method has been approved by the FDA and validated by San Diego Blood Bank for bacterial detection in platelet components. As long as appropriate specimen is available, positive test results are submitted for further testing and identification of the organism.

## **Personnel**

Personnel are initially trained in the department following policies and procedures. They are also trained in San Diego Blood Bank safety and disaster and cGMP practices. Competency is performed as per CMS/CLIA regulations. San Diego Blood Bank trains and develops personnel to have an effective and efficient working ability following all written policies and procedures.

## **Disaster Planning**

San Diego Blood Bank has a disaster plan and will work jointly with AABB, America's Blood Centers and California Blood Bank Society to provide blood as necessary during a disaster. Additionally the blood center is the Area Emergency Operations Center for Southern California (one of three in the state). The San Diego Blood Bank's disaster plan includes a Business Continuity Plan.